iTAB (Individualized Texting for Adherence Building)

Evidence-Based for PrEP Medication Adherence/Persistence

INTERVENTION DESCRIPTION

Goal of Intervention
- Improve PrEP adherence

Intended Population
- HIV-negative men who have sex with men (MSM) and transgender women who are at high risk for HIV

Brief Description

iTAB is an individual-level, mobile-health intervention that uses two-way, fully automated daily personalized health promotion and "factoid" text messages to improve PrEP adherence. Participants choose messages consistent with their preferences from 440 different messages or create their own messages. Each message ends with a prompt to respond with a single letter indicating whether participants have taken or not taken PrEP. Participants receive daily messages at a personally selected time for taking PrEP. Both iTAB and the comparison (Standard of Care) group receive, at baseline visits, a brief HIV prevention and adherence counseling and PrEP medications consistent with the Centers for Disease Control and Prevention (CDC) guidelines.

Theoretical Basis
- Behavioral Theory

Intervention Duration
- Daily text messages delivered over 48 weeks

Intervention Setting
- Mobile phone

Deliverer
- Text message system
- Study staff

Delivery Methods
- Text messages
- Counseling

Structural Components

There are no structural components reported for this study.

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. Please contact **Sheldon Morris**, California Collaborative Treatment Group, UC San Diego Antiviral Research Center, 200 Arbor Drive, Mail Code 8208, San Diego, CA 92103.

Email: shmorris@ucsd.edu for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location Information
The original study was conducted in Los Angeles and San Diego, CA between February 2013 and February 2015.

Key Intervention Effects
- Improved PrEP adherence

Study Sample
iTAB (n = 200)
- *75% White, 31% Hispanic, Latino or Latina, 13% Black or African American, 4% Asian, 7% multiple, 2% other*
- *99% male; 1% transgender women*
- *Mean age of 35.1 years, SD=9.8*
- *70 % condomless sex with ≥3 HIV+/unknown partners past 3 months*
- *15% condomless sex with ≥1 partner and had an STI in past 6 months*
- *27% any STI*

Standard of Care (n = 198)
- *77% White, 29% Hispanic, Latino or Latina, 14% Black or African American, 3% Asian, 5% multiple, 2% other*
- *100% male*
- *Mean age of 35.4 years, SD=8.7*
- *69% condomless sex with ≥3 HIV+/unknown partners past 3 months*
- *18% condomless sex with ≥1 partner and had an STI in past 6 months*
- *25% any STI*

Note: Percentages may not add up to 100% due to rounding and race/ethnicity are not mutually exclusive

Recruitment Settings
Four southern California medical centers

Eligibility Criteria
MSM and transgender women were eligible if they tested HIV-negative (confirmed by a negative fourth-generation antigen-antibody assay or a third-generation antibody assay plus HIV nucleic acid amplification test [NAAT]) and had a persistent elevated risk for HIV infection determined as having (1) ≥1 HIV-infected partner for ≥4 weeks; (2) condomless anal intercourse with ≥3 HIV-positive or unknown status male partners in prior 3 months; or (3) condomless anal sex with ≥1 male partner plus a sexually transmitted infection (STI) in prior 3 months. Those with active hepatitis B and/or signs or symptoms of acute HIV infection were excluded.

Assignment Method
Participants (N = 398) were randomized 1:1 to individualized texting for adherence building (iTAB) (n = 200) or Standard of Care (SoC) (n = 198); randomization was stratified by study site and assigned at baseline through an electronic data capture system.

Comparison Group
The SoC participants received, at their baseline visits, a brief HIV prevention and adherence counseling with provision of PrEP meds by study staff consistent with CDC guidelines.

Relevant Outcomes Measured and Follow-up Time

- PrEP medication adherence/persistence was measured using dried blood spot (DBS) tenofovir diphosphate (TFV-DP) concentrations at week 12 visit and, if continued on PrEP past week 12, every 12 weeks through the last study visit at week 48 (i.e., week 24, 36, 48). Adherence/persistence was measured using the following categories:
  - "Near-perfect PrEP adherence" (seven doses of tenofovir disoproxil fumarate (TDF) in the past week): Intracellular TFV-DP drug concentrations >1246 fmol/punch;
  - "Minimally acceptable adherence" (four or more doses of TDF in the past week): Intracellular TFV-DP drug concentrations >719 fmol/punch;
  - Dosing in the past 24 hours: Plasma emtricitabine (FTC) drug concentrations >350 ng/ml, providing an indication of TDF/FTC dosing in the last 24 hours.

Participant Retention

- At 12 weeks*
  - iTAB: 91% (181 of 200)
  - SoC: 91% (180 of 198)
- At 48 weeks
  - iTAB: 79% (158 of 200)
  - SoC: 84% (166 of 198)

Significant Findings on Relevant Outcomes

- A significantly greater percentage of iTAB participants exhibited near-perfect PrEP adherence than SoC participants at 48 weeks post-initiation (51% vs. 37.4%, p = 0.02).
- A significantly higher proportion of iTAB participants exhibited dosing in the past 24 hours than SoC participants at 12 weeks post-initiation (47.5% vs. 33.3%, p = 0.007).
- Mean plasma FTC concentrations were consistently higher in the iTAB arm compared to the SoC arm, but this was only statistically significant at week 12 (400.3 ng/mL vs. 299.3 ng/mL; p = 0.009).
- iTAB participants were more adherent for the near-perfect PrEP adherence outcome after adjusting for confounders than SoC participants (odds ratio [OR] = 1.56, 95% CI: 1.00-2.42).

Strengths

- None reported

Considerations

Note: The TFV-DP concentrations outcome on near-perfect PrEP adherence was significant at week 48, but the plasma FTC concentrations outcome was only significant at week 12.

Additional significant positive findings on non-relevant outcomes

- None reported

Non-significant findings on relevant outcomes

- There were no significant intervention effects for minimally acceptable adherence at weeks 12 and 48.
- There were no significant intervention effects for near-perfect adherence at week 12.
- Differences in the proportions of those exhibiting plasma FTC concentrations > 350 ng/mL in the past 24 hours at week 12 did not persist at 24, 36, and 48 weeks.
- Two HIV seroconversions occurred in the iTAB arm (HIV incidence rate, 0.7 per 100 person-years vs. 0; p = 0.25); both persons reported discontinuing the drugs prior to seroconversion.

Negative findings
- None reported

Other related findings
- Despite randomization, the iTAB arm as compared to the SoC arm (1) had lower education, HIV literacy, and likelihood of reporting income; (2) were less likely to have had an HIV-infected sexual partner for the past 4 weeks or longer; (3) had higher levels of depressive symptoms (PHQ-9); and (4) had higher mean sexual compulsivity scores.

Implementation research-related findings
- None reported

Process/study execution findings
- 74 participants terminated the study prior to week 48 (42 [21%] in iTAB vs. 32 [16.2%] in SoC; p = 0.25)
    - 2 persons became HIV infected
    - 38 subjects requested to withdraw from the study
    - 2 adverse events
    - 32 missed 2 consecutive visits

Adverse events
- Two serious adverse events occurred: pancreatitis, unrelated to study drug, and Fanconi syndrome, related to the study drug.

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*Information obtained by the study author.

REFERENCES AND CONTACT INFORMATION

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Researcher: Sheldon R. Morris, MD
California Collaborative Treatment Group
University of California, San Diego Antiviral Research Center
200 Arbor Drive, Mail Code 8208
San Diego, CA 92103

Email: **shmorris@ucsd.edu**